REMARKS

The invention herein is directed to a means for dispensing a single unit dose of an oxygen-sensitive drug without exposing the remaining unit dosages to oxygen, in particular, a pharmaceutical packaging construction having an oxygen-absorber incorporated therein.

Claim 1 has been amended to incorporate dependent claims 4, 7 and 19. Claim 1, as amended, now states the degradation or discoloration of the oxygen sensitive drug is reduced by at least about 20%, the oxygen absorber is a UV activated absorber, and the oxygen content of the air surrounding the oxygen-sensitive drug is maintained at a level less than or equal to about 10.0% for about two years. Dependent claims 4, 7 and 19 have been canceled. Strictly in an effort to expedite prosecution herein, claims 5, 6, 19 and 22-34 have also been canceled. Applicant expressly reserves the right to pursue the subject matter of such canceled claims in divisional applications. It is believed no new matter has been added by the present amendments.

After the amendments herein, the claims pending in this application number 1-3, 8-18 and 20-21.

Claims 1, 4, 11-15 and 18 have been rejected as being anticipated by U.S. 5,682,626 to Green et al. Claims 1-5, 7-10,19-22, 24 and 25 have been rejected as being anticipated by U.S. 6,279,736 to Hekal. Claims 16, 17, 23, 27-33 and 34 have been rejected under 35 USC 103 as being unpatentable over Hekal in view of Green et al. Claims 6 and 26 have been rejected under 35 USC 103 as being unpatentable over Hekal in view of U.S. 6,133,361 to Hatakeyama et al. The Examiner's comments have been carefully considered, and the rejections are respectfully traversed.

To constitute anticipation, all material elements of a claim must be found in one prior art source. In re Marshall, 198 USPQ 344 (CAFC 1978). In order to sustain a finding of anticipation, the disclosure of a prior art reference must be adequate to enable possessionof

desired subject matter, and a reference that names or describes desired subject matter does not anticipate if the subject matter cannot be produced without undue experimentation. Even if the claimed invention is disclosed in a printed publication, that disdosure will not suffice as prior art if it is not enabling. Elan v. Mayo Foundation, 68 USPQ2d 1373 (Fed.Cir. 2003).

Moreover, in determining whether the subject matter as a whole is obvious, all evidence bearing on the subject must be considered, In re Wiggins, 158 USPQ 199 (CCPA 1968), including all differences, whatever their nature, between the subject mattter sought to be patented and the prior art In re Krazinski et al, 146 USPQ 25 (CCPA 1965), In re Rinehart, 189 USPQ 143 (CCPA 1976).

The Examiner's attention is respectfully directed to the attached informal drawing of the present invention, which is submitted for clarification. In the particular embodiment of Figure A, a cross section of a single unit of a blister package is shown. The top of this cross section shows the blister disposed on top of the dosage form, while the bottom of the dosage form in encased with the lid. A single layer that reduces oxygen permeability comprises the blister. When viewed in order from the dosage form, Figure A shows the lid comprises a thermal adhesive layer that serves to bond the blister and lid together, an oxygen absorbing layer and finally a base layer (typically comprised of an aluminum foil). The permeability of oxygen through the heat seal is sufficient to enable the oxygen surrounding the dosage form to be effectively removed by the oxygen-absorbing layer. In an alternative embodiment, both the heat seal and oxygen absorbing layers can be a single layer serving both functions.

In Figure B, a cross-section of a second embodiment of the invention is shown. In this configuration, the blister comprises (when viewed from the top) a low oxygen-permeability layer, an oxygen absorbing layer and a contact layer having high oxygen permeability (either by virtue of its material properties or its thickness, or both). The oxygen permeability of the contact layer is sufficient to allow oxygen from around the dosage form to be removed by the oxygen-absorbing layer. In an alternative embodiment, the oxygen absorbing layer and the contact layer can comprise a single layer serving both functions. The lid in this configuration is generally a standard blister lid comprising a heat seal and a low permeability layer, generally an aluminum foil.

Green et al. disclose a method of forming and packaging a patch including a drug filled reservoir in an inert atmosphere. Applicant herein does not require packaging in an inert atmosphere. This is because the oxygen absorbing layer removes oxygen from the atmosphere surrounding the dosage form.

Hekal discloses a process for providing moisture permeable channels so that moisture can reach desiccants embedded in the blister packaging. In contrast, Applicant's invention does not require such channels since oxygen is quite permeable. In the present invention, the blister becomes an active oxygen absorber by UV light activation. In contrast, the Hekal blister package becomes active from deposition of the material in the blister. In practical terms, Applicant's blister can be formed and stored under ambient conditions and only activated immediately before use. Hekal requires the deposition of absorbing material right before use or storage in an inert atmosphere. Hekal's deposited material may come into direct contact with the active drug which may lead to safety and/or toxicity issues. Unlike Hekal, Applicant's oxygen absorbing material can be imbedded (since light only needs to penetrate to activate) thereby eliminating any potential safety and/or toxicity issues.

Applicant submits the references cited by the Examiner as anticipatory to the invention herein do not meet the statutory requirement as set forth above. None of the cited references disclose every element of Applicant's invention and none of the references enables a skilled artisan to make the present invention without undue experimentation, as is required by 35 USC 102. Clearly, the statutory mandate for a finding of anticipation has not been met. Withdrawal of all rejections under 35 USC 102(b) is requested.

The Examiner alleges claims 16, 17, 23, 27-33 and 34 are unpatentable over Hekal in view of Green et al. By the present amendments, claims 23-34 have been canceled, obviating the rejection. With respect to the pending claims, the Examiner's rejection under 35 USC 103 is based on the belief that it would have been obvious to combine the disclosure of Green et al with Hekal to arrive at Applicant's invention. Applicant respectfully disagrees.

Applicant's statements and comments from above relating to Green et al. and Hekal are incorporated by reference in this regard. That is, unlike Green, Applicant does not require packaging in an inert atmosphere; rather the oxygen absorbing layer removes oxygen from the atmosphere surrounding the dosage form. Unlike Hekal, Applicant's invention does not require moisture permeable channels to allow moisture to reach desiccants embedded in the blister packaging since oxygen is quite permeable. Nor does Applicant require the deposition of material in the blister for blister activation. Applicant's blister becomes an active oxygen absorber by UV light activation.

It is submitted the rejection under 35 USC 103 is based on pure speculation or the unsupported opinion of the Examiner derived by hindsight knowledge of Applicant's specification since there is no teaching or suggestion in the references to make the combinations alleged by the Examiner to be obvious. The Examiner is suggesting an "obvious to try" concept. But, such a concept does not render Applicant's invention as presently claimed unpatentable.

Because chemistry is often an empirical science, it is easy to characterize inventions in the field as being the result of "routine testing" or having been "suggested". However, while obviousness is tested by "what the combined teaching of the references would have suggested to those of ordinary skill in the art" In re Keller, 208 USPQ 871, 881 (CCPA 1981), it "cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, or suggestion supporting the combination" ACS v. Montefiore, 221 USPQ 929, 933 (Fed. Cir. 1984).

Approaches to obviousness determinations which focus merely on identifying and tabulating "missing elements" in hindsight retrospect "imbue one of ordinary skill in the art

with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge," and "fall victim to the insidious effect of hindsight syndrome where that which only the inventor taught is used against its teacher." Gore v. Garlock, 220 USPQ 303 (Fed. Cir. 1983). "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention."In re Fine, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988).

> The question of nonobviousness is a simple one to ask, but difficult to answer . . .The difficulty which attaches to all honest attempts to answer this question can be attributed to the strong temptation to rely on hindsight while undertaking this evaluation. It is wrong to use the patent in suite as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit. Monday morning quarterbacking is quite improper when resolving the question of nonobviousness . . .

Accordingly, Applicant respectfully submits that all of the claims as presently amended are clearly patentable over Hekal and Green et al. and the rejections under 35 USC 103 have been overcome. Withdrawal of such rejections is requested.

This application is believed to be in condition for allowance. Favorable consideration is respectfully requested.

The Commissioner is hereby authorized to charge any fees required under 37 C.F.R. §§ 1.16 and 1.17, or to credit any overpayment to Deposit Account No. 16-1445.

Respectfully submitted,

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